510(k) Summary for Reflex™ Anterior Cervical Plate System – Additional Indications

Proprietary Name:	Reflex™ Anterior Cervical Plate System
Common Name:	Anterior Cervical Plate System
Proposed Regulatory Class:	Class II
Classification Name and Reference:	Spinal Invertebral Body Fixation Orthosis 21 CFR §888.3060
Device Product Code:	87 KWQ: Appliance, Fixation, Spinal Intervertebral Body
For Information contact:	Karen Ariemma Regulatory Affairs Specialist Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677 Telephone: (201) 831-5718 Fax: (201) 831-6038 Email: kariemma@howost.com
Date Summary Prepared:	May 30, 2003

The purpose of this premarket notification is to add indications to the Reflex™ Anterior Cervical Plate (ACP) System.

Predicate Device Information:

The Reflex™ ACP System consists of bone plates and screws. Both components are available in a variety of lengths in order to accommodate patient physiology. The components are fabricated from titanium alloy. The implants will be provided non-sterile. The following system was already determined substantially equivalent for the desired indications: Synthes' Cervical Spine Locking Plate (CSLP) System.

Intended Use:

The Reflex™ ACP System is intended for anterior intervertebral screw fixation of the cervical spine at levels C2-T1. The system is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with the following indications: Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), trauma (including fractures), tumors, deformities or curvatures (including kyphosis, lordosis or scoliosis), pseudoarthrosis, failed previous fusion, decompression of the spinal cord following total or partial cervical vertebrectomy, spondylolisthesis and spinal stenosis.

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Performance Data:

Static and fatigue test results show the Reflex ACP System demonstrated comparable mechanical properties to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 8 2003

Ms. Karen Ariemma
Regulatory Affairs Specialist
Howmedica Osteonics Corporation
59 Route 17
Allendale, NJ 07401-1677

Re: K031702
Trade/Device Name: Reflex™ Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: May 30, 2003
Received: June 2, 2003

Dear Ms. Ariemma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 031702

Device Name: Reflex Anterior Cervical Plate System

The Reflex ACP System is intended for anterior intervertebral screw fixation of the cervical spine at levels C2-T1. The system is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with the following indications:

- Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Trauma (including fractures)
- Tumors
- Deformities or curvatures (including kyphosis, lordosis or scoliosis)
- Pseudoarthrosis
- Failed previous fusion
- Decompression of the spinal cord following total or partial cervical vertebrectomy.
- Spondylolisthesis
- Spinal Stenosis

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ OR Over-The-Counter Use____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031702